

REMARKS

In accordance with the above amendments, certain corrections have been made in the specification. In addition, claims 48 and 61 have been amended and claims 58-59 and 72-76 have been withdrawn. Thus, claims 48-57, 60-71, 77 and 78 remain under consideration in this application.

Claim Rejection - 35 USC § 101

The rejection of claims 73 and 74 under 35 USC § 101 is believed to have been rendered moot inasmuch as these are among the claims that have been withdrawn from consideration at the present time.

Claim Rejection - 35 USC § 112, Second Paragraph

The rejection of claims 50 and 62 under 35 USC § 112, second paragraph is also believed to have been overcome by the amendments to these claims in which the proper antecedent has been added to claim 48. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

Claim Rejection - 35 USC § 112, First Paragraph

Claims 48-57, 60-71 and 77-78 have been rejected under 35 USC § 112, first paragraph because, although the Examiner agrees that the specification is enabling for a method of promoting apoptosis in a cell comprising introducing a nucleotide *in vitro*, it does not reasonably provide enablement for a method of

promoting apoptosis in a cell *in vivo*. This rejection is respectfully traversed.

As the Examiner has indicated, there are several factors which need to be considered in determining whether there is sufficient evidence to support a determination that a disclosure satisfies the enabling requirement and whether any necessary experimentation is "undue".

Applicants believe that the instant specification provides adequate guidance for one skilled in the art to predict the success of the invention, not only *in vitro*, but also *in vivo*. When one combines the success achieved *in vitro* with the high level of ordinary skill in the art, it is believed that the overwhelming expectation would be that it would succeed *in vivo* without undue additional experimentation. Thus, it is believed that the descriptions provided in the instant specification do provide adequate guidance for those skilled in the art to enable the invention to be practiced *in vivo*. It is well recognized that one need not provide examples of each and every method step in order to enable one skilled in the art to practice an invention, particularly when the level of skill in the art is quite high, as is the case with the present subject matter.

Consequently, it is believed that the teachings of the present specification are indeed sufficient to enable both *in vitro* and *in vivo* therapeutic methods.

Claim Rejection - 35 USC § 102

Claims 48, 51-54, 62-64 and 67-68 have been rejected under 35 USC § 102(a) as being anticipated by Lewis et al (Bioconjugate Chemistry, 2002, 13:1176-1180). While Lewis et al do discuss an anti-Bcl-2 antisense PNA conjugate that may be coupled to a peptide for a possible delivery which may be of interest, it neither enables nor suggests how such delivery could be accomplished. Thus, it clearly falls short of teaching the presently claimed invention.

It is also noted that claims 48-50, 52-53, 55-56, 62-63 and 67-68 have been rejected under 35 USC § 102(e) as being anticipated by Buluwela et al (WO 03/010308 A2). This rejection is also respectfully traversed. While Buluwela et al is also of interest, it only broadly teaches an approach similar to that of the present invention and does not teach or suggest other claim limitations.

Claims 48-56, 59, 62-63 and 67-68 are rejected under 35 USC § 103 as being anticipated by Hart et al (WO 03/033701 A1). This rejection is also respectfully traversed. Applicants do not believe that this reference anticipates any of the present claims, however, they are prepared to investigate the relative dates to determine whether Hart et al is of good date to be used as a reference.

Claim Rejection - 35 USC § 103

It is further noted that claims 48-57, 60-65 and 67-68 have been rejected under 35 USC § 103(a) as being unpatentable over Wolffe et al (WO 02/26960 A2) in view of Reed (USPN 5,831,066) and Li et al (Genes & Development, 2002, 16:687-692). This rejection is also respectfully traversed.

A review of the combination of references cited in this rejection is not believed to lead one to any of the present claims absent a clear inventive step. Whereas a high degree of skill can be attributed to those skilled in the particular art at hand, it is not believed that one would have modified the method of Wolffe et al to arrive at the present invention based on the disclosure of the additional references.

Given the above amendments, taken together with the remarks herein, applicants are convinced that the present claims should be allowable over the cited references, taken either singularly or in combination, and reconsideration and allowance of the claims is respectfully requested.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment in response to the Official Action of September 12, 2008, together with a Petition for a three-month extension of time and a check in the amount of \$1110.00, in application Serial No. 10/536,664, filed on January 17, 2006, of John David Jenkinson et al, entitled "CONTROL OF APOPTOSIS" are being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Mail Stop Non-Fee Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, postage prepaid, on March 11, 2009.

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on behalf of C. G. Mersereau
Attorney for Applicant

Date of Signature: March 11, 2009